

# EXHIBIT 1

**From:** Jonathan Reeve <jonathan.reeve@tn.gov>

**To:** "Blatt, Ruth (CMS/CMCS) (Ruth.Blatt@cms.hhs.gov)" <Ruth.Blatt@cms.hhs.gov>

**Cc:** Susie Baird <susie.baird@tn.gov>, "Aaron C. Butler" <aaron.c.butler@tn.gov>, "john.coster@cms.hhs.gov" <john.coster@cms.hhs.gov>, James Hailey <James.Hailey@tn.gov>, "Kenni.Howard@cms.hhs.gov" <Kenni.Howard@cms.hhs.gov>, Gabe Roberts <Gabe.Roberts@tn.gov>

**Subject:** RE: Coverage of drugs not on PDL

**Date:** Fri, 29 Jan 2016 11:22:39 -0600

**Importance:** Normal

**Attachments:** Letter\_to\_CMS\_-\_BEN\_15-001.pdf; Letter\_to\_CMS\_-\_BEN\_15-001(1).pdf

**Inline-Images:** image001.jpg

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Good morning, Ms. Blatt. This message is intended to respond to CMS's questions on two issues:

1. TennCare Policy BEN 15-001, which was the subject of the telephone discussion on 12/18/15; and
2. SPA TN-15-0002, for which CMS sent follow-up RAI questions on 1/15/16.

With regard to Policy BEN 15-001, please find attached a letter from John G. (Gabe) Roberts, General Counsel for TennCare. This letter outlines the basis for the review process by which a new drug or an existing drug with a new indication is integrated into the TennCare formulary.

With regard to SPA TN-15-002, CMS has asked the State to elaborate on its responses to RAI Questions 17 and 18b in light of the telephone discussion of 12/18/15. These clarifying RAI responses are as follows:

**17. Does the prior authorization requirement within the state plan make medically necessary prescription drugs available to financially needy individuals?**

**State response:** The prior authorization requirement within the state plan makes medically necessary prescription drugs available to financially needy individuals, assuming that the drugs in question are covered by the TennCare program. Of FDA-approved drugs from manufacturers that have entered into a rebate agreement with the federal government, two types are not covered by the TennCare program: 1) drugs that federal law—Section 1927(d)(2) of the Social Security Act—allows the State to restrict and 2) drugs for which the TennCare Pharmacy Advisory Committee has not completed a therapeutic class review.

**18.**

- b. Will all covered outpatient drugs that are not included on the PDL remain available pursuant to prior authorization, consistent with section 1927(d)(5) of the Act?**

**State response:** The State understands the phrase “covered outpatient drugs that are not included on the PDL” to mean “covered outpatient drugs that do not have preferred status in the TennCare program.” (As stated in the response to RAI Question 17 above, drugs for which the TennCare Pharmacy Advisory Committee has not completed a therapeutic class review and drugs that the State may restrict pursuant to federal law are not considered “covered” and, therefore, are beyond the scope of CMS’s question.)

Covered outpatient drugs that do not have preferred status in the TennCare program remain available via the prior authorization process. As noted in the State’s responses to RAI Questions 18d and 18f, there are certain contexts in which non-preferred drugs may be obtained without undergoing the customary prior authorization procedures (e.g., continuation of a medication originally prescribed during an inpatient hospitalization until the course of treatment is complete).

If you have questions, please let me know.



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**From:** Blatt, Ruth (CMS/CMCS)  
**Sent:** Monday, January 25, 2016 12:03 PM  
**To:** Susie Baird ([susie.baird@tn.gov](mailto:susie.baird@tn.gov)); Aaron C. Butler ([aaron.c.butler@tn.gov](mailto:aaron.c.butler@tn.gov)); James Hailey ([James.Hailey@tn.gov](mailto:James.Hailey@tn.gov))  
**Cc:** Howard, Kenni L. (CMS/CMCHO); Coster, John M. (CMS/CMCS)  
**Subject:** Coverage of drugs not on PDL

Hi Tennessee,

We’re following up on our telephone discussion from December 18<sup>th</sup> during which you indicated that you would have information for us by mid-January regarding Tennessee’s coverage of drugs that are not on the PDL. We additionally sent follow-up questions to the RAI responses you provided for SPA TN 15-0002, which address the same issue (see below).

We’d appreciate hearing from you as soon as possible. We’d like to resolve the issues discussed on the December call and additionally, In order to proceed with our review of SPA TN 15-0002, we need to understand your policy for coverage of drugs that are in the Medicaid Drug Rebate Program but not on Tennessee’s PDL and how that policy complies with federal law.

Thanks,

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**From:** Howard, Kenni L. (CMS/CMCHO)  
**Sent:** Friday, January 15, 2016 1:07 PM  
**To:** Susie Baird ([susie.baird@tn.gov](mailto:susie.baird@tn.gov)); Aaron C. Butler ([aaron.c.butler@tn.gov](mailto:aaron.c.butler@tn.gov))  
**Cc:** Blatt, Ruth (CMS/CMCS)  
**Subject:** TN 15-0002

Happy Friday!

Please see the questions below from the pharmacy team regarding SPA 15-0002. If you would like to discuss these questions or need clarification, please feel free to contact us.

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Thank you for your response to the RAI for SPA TN-15-0002 and thank you for our call on December 18<sup>th</sup> regarding your policy on drug coverage of Covered Outpatient Drugs. The responses to the RAI seem fine although we would like some clarification on one point, as it relates to our discussion on December 18<sup>th</sup>.

Question 17 asks if the prior authorization requirement within the state plan makes medically necessary prescription drugs available to financially needy individuals. Your response was yes, it does, *assuming the drugs in question are covered by the TennCare program*.

Question 18b. asks if all covered outpatient drugs that are not included on the PDL remain available pursuant to prior authorization and your response was yes, with the only restriction being those drugs which may be restricted per section 1927(d)(2).

The answer to 18b. seems to comply with our understanding of the statute, as we discussed on our December 18<sup>th</sup> call. However, can you clarify the part of the response to question 17 that references "assuming the drugs in question are covered by the TennCare program"? Does this indicate that there are drugs, other than those which may be restricted pursuant to section 1927(d)(2), that may not be covered by TennCare? Or, is that phrase limited to only the drugs covered under section 1927(d)(2)?

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Thank you for your time.

Kenni

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